FURLS Device Registration & Listing

Initial Registration

U.S. Food and Drug Administration
Center for Devices and Radiological Health

Division of Industry and Consumer Education (DICE)

Instructions for

Domestic, First Registration in Account

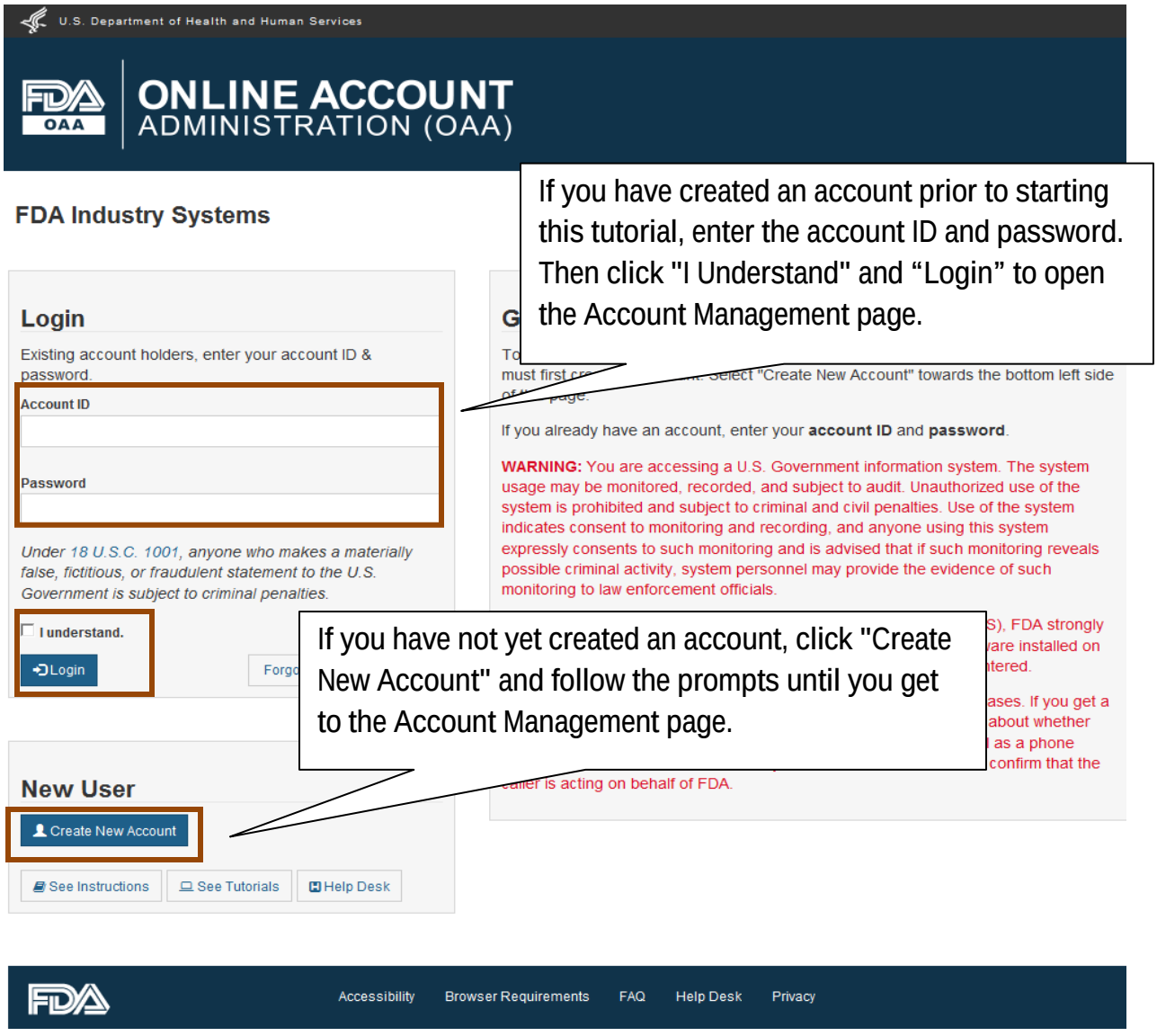
This tutorial should only be used when 1) registering a facility that is located in the U.S.; 2) you have already paid the annual registration user fee and received your Payment Identification Number (PIN) and Payment Confirmation Number (PCN); and, 3) the owner/operator has no other registered facilities.

Step 1: Click https://www.access.fda.gov/oaa/ to open the FDA Industry Systems Website.

If you have created an account prior to starting this tutorial, enter the account ID and password, click “I Understand” and then click on the Login button.

If you have not yet created an account, click on “Create New Account” and follow the prompts until you get to the Account Management page.

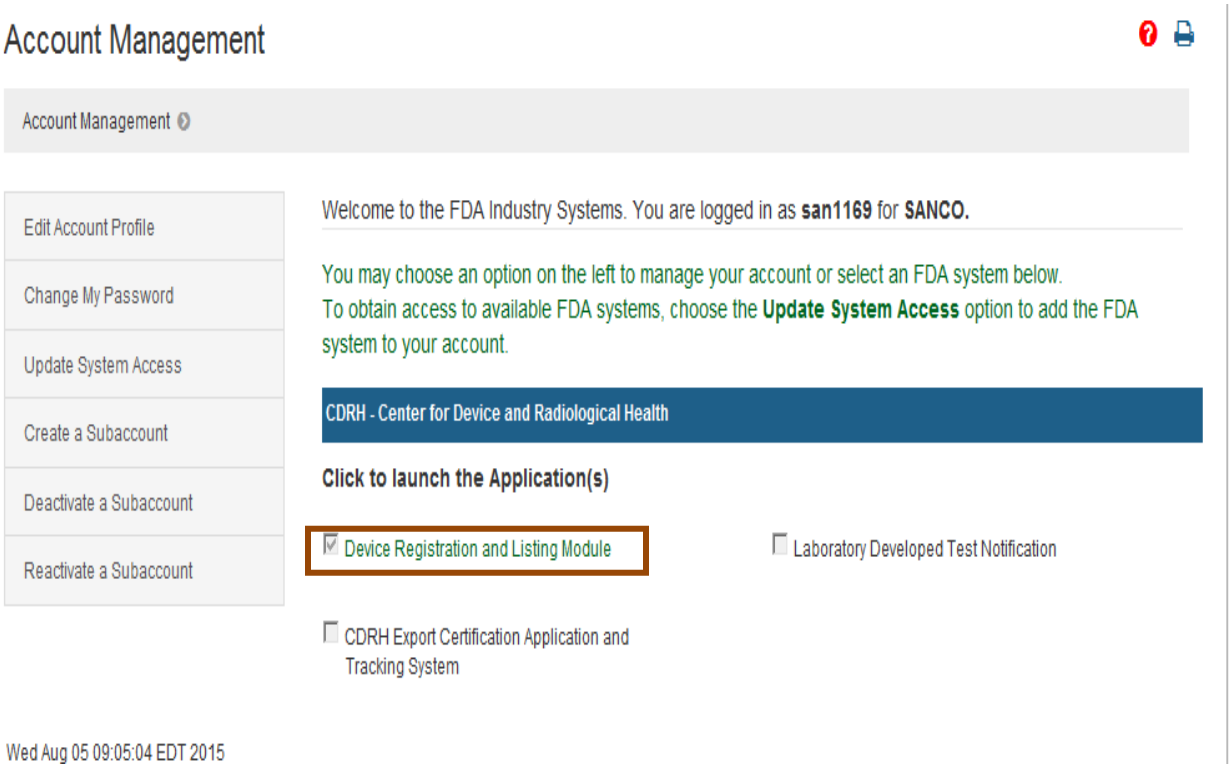
Proceed to Step 2.



Step 2: Click "Device Registration & Listing" to begin the registration.

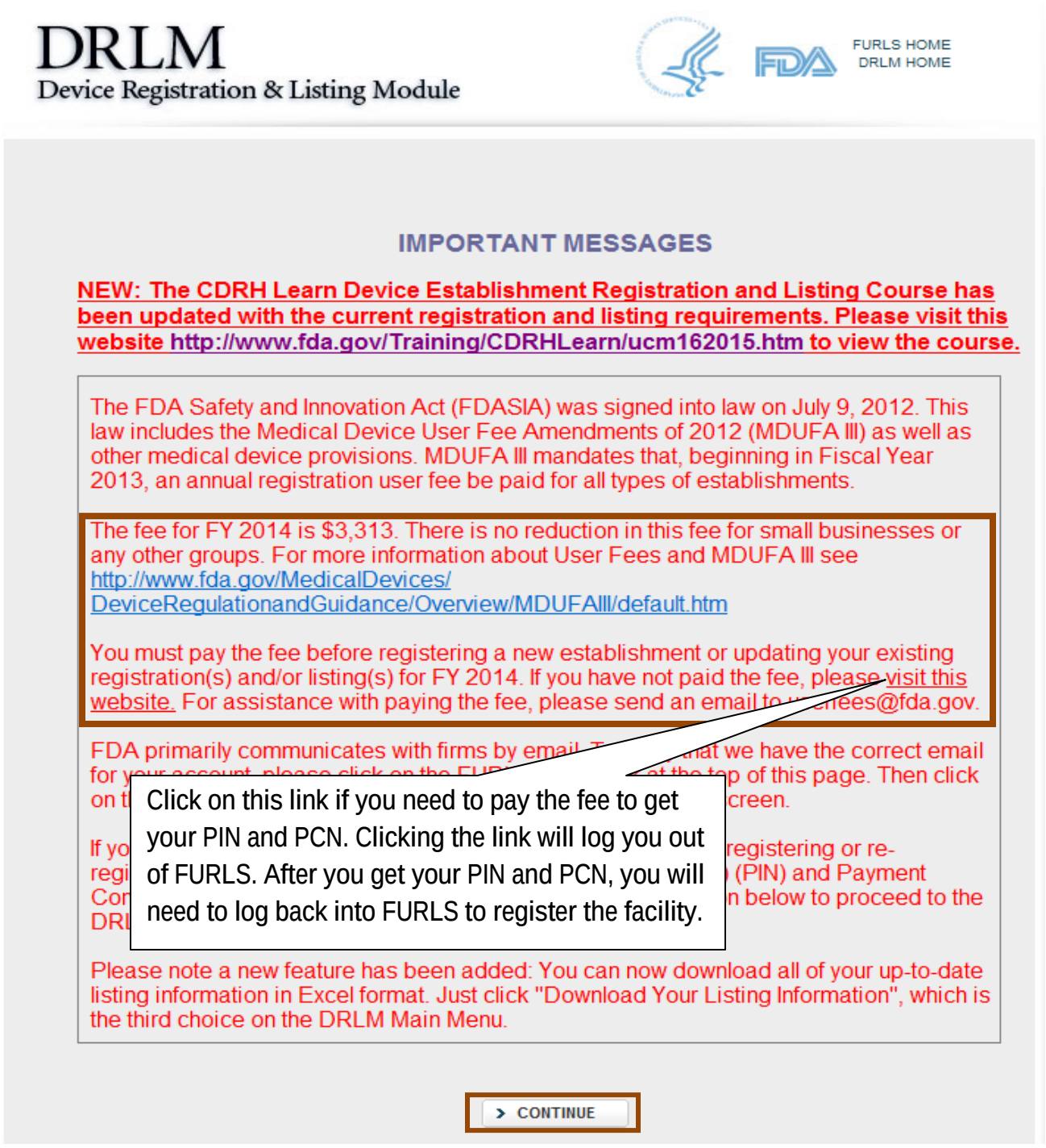
Proceed to Step 3.

Note: If you have only created an owner/operator account, the same contact information will appear on the registration record for both the owner/operator and official correspondent. If a different person is acting as official correspondent, you must create a sub account for that person before beginning the registration process.

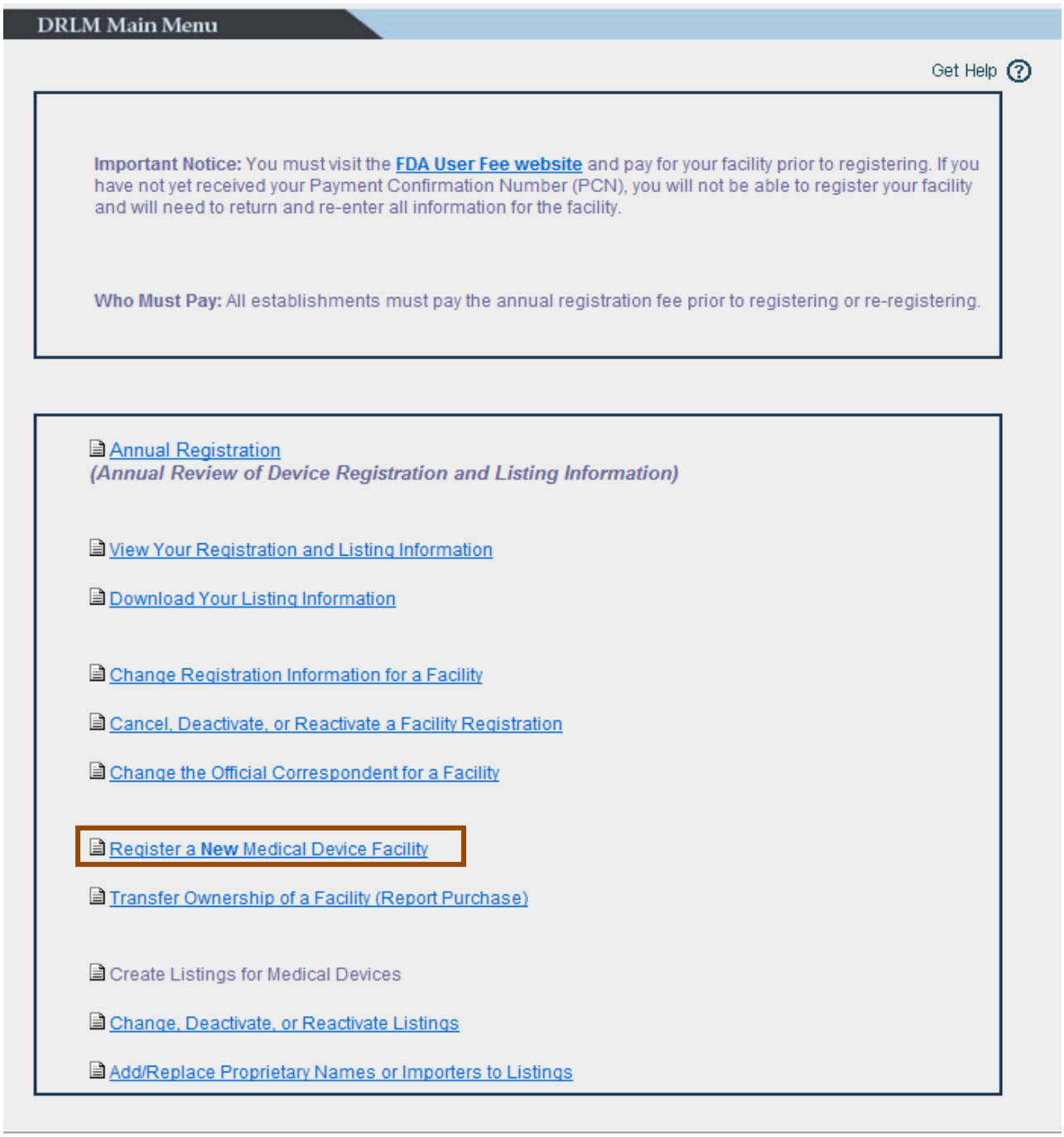


Step 3: Review “Important Messages” and click "Continue" to proceed to the DRLM Main Menu. Proceed to Step 4.

Note: You must pay the fee to receive your Payment Identification Number (PIN) & Payment Confirmation Number (PCN) before you can register your facility.



Step 4: Review the “Important Notice” at the top of the DRLM Main Menu screen. Click on "Register a New Medical Device Facility”. Proceed to Step 5.



Step 5: If the facility was previously registered, enter the Registration Number or Owner/Operator Number and click "Search." If the facility has not been registered, leave the search fields empty and click "No Existing Registration or OO Number" and follow the prompts to register. Proceed to Step 6.

Step 6: The Registration Requirements page provides links to pay the annual registration user fee, to determine if your product is exempt, to get your FDA product codes, and to register your facility. If you have both your PIN and PCN, and have determined your device listing information, including the facility activities, click “Register My Facility”. Proceed to Step 7.

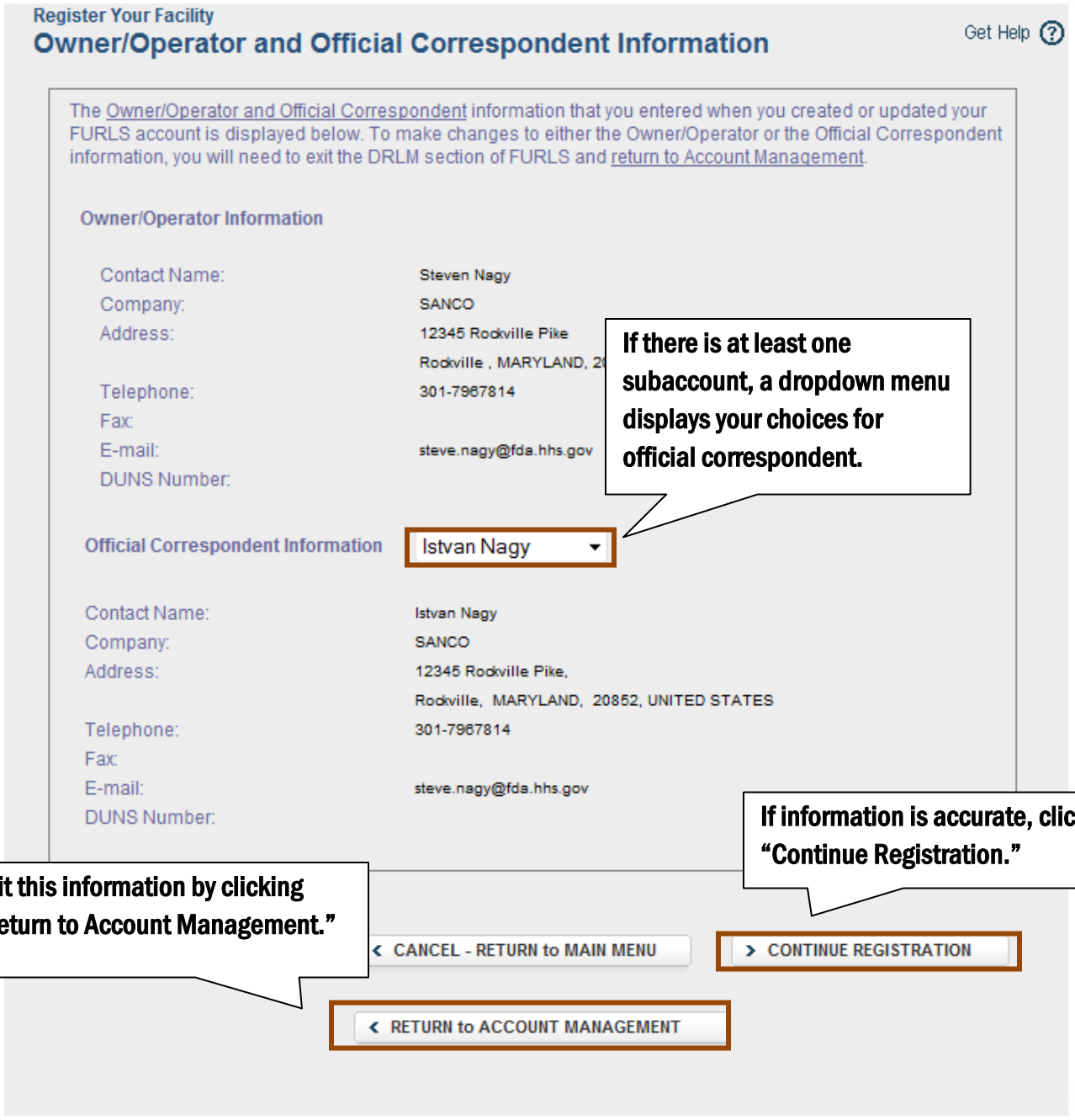
Step 7: On the Transfer of Ownership page, select "Yes" or "No" to indicate if the registration is for a facility that you have acquired that is already registered by another company. Then click “Continue Registration”. Proceed to Step 8.

If you select “Yes” the system will take you through the Transfer of Ownership process. Follow the prompts through the transfer process. If you need assistance, contact reglist@CDRH.FDA.GOV.

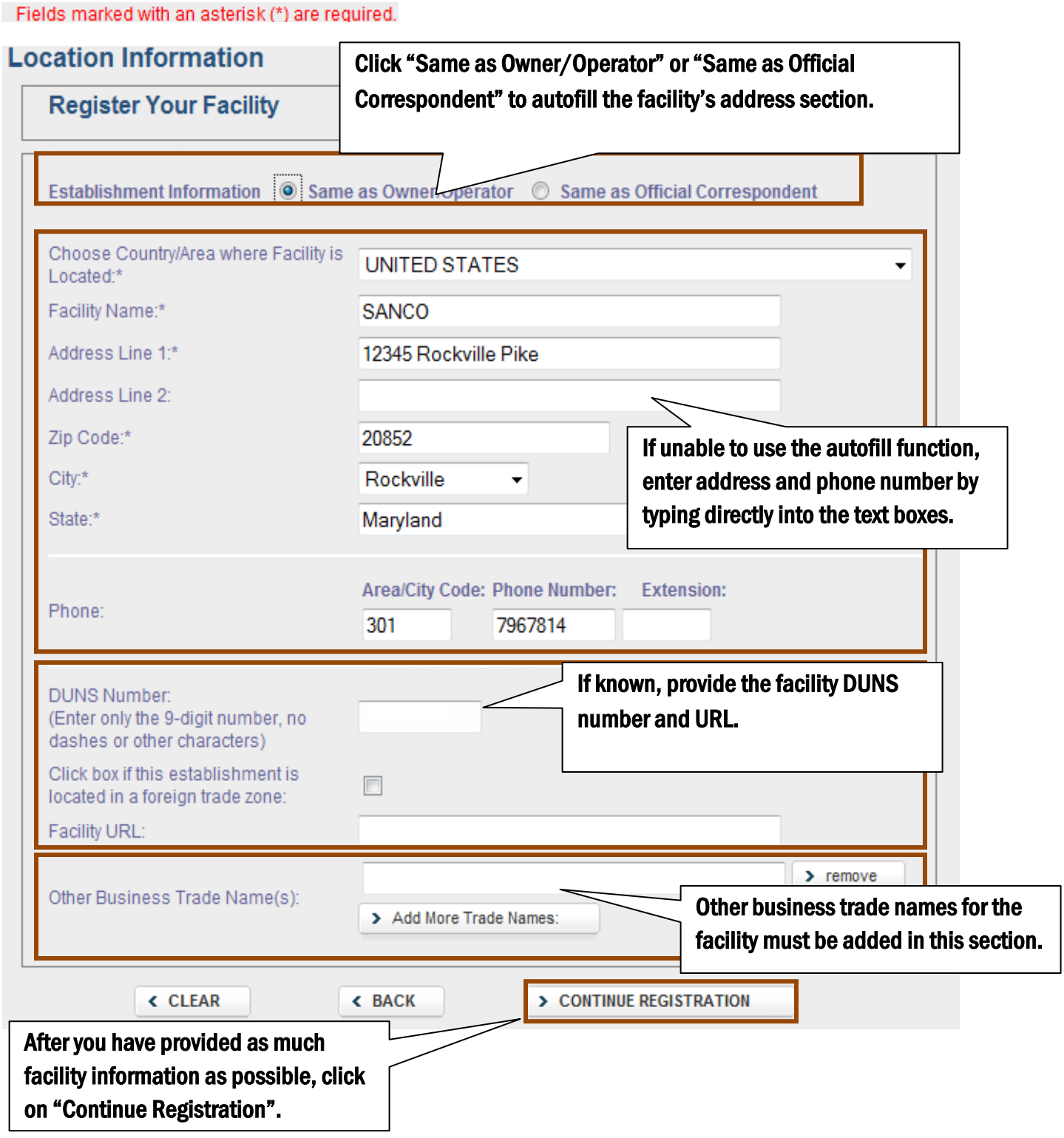
Step 8: The Owner/Operator and Official Correspondent Information page displays contact information for both owner/operator and official correspondent. Review for accuracy and then click "Continue Registration." Proceed to Step 9.

Edit: Edit the information on this form by clicking "Return to Account Management." When you have completed your edits, return to Step 2.

Subaccounts: If there are no subaccounts, the owner/operator contact person's information will display for both the owner/operator and the official correspondent. If you created sub-accounts, the names associated with the sub-accounts will appear in the dropdown menu along with the owner operator contact person. You can choose any of these people to act as the official correspondent.

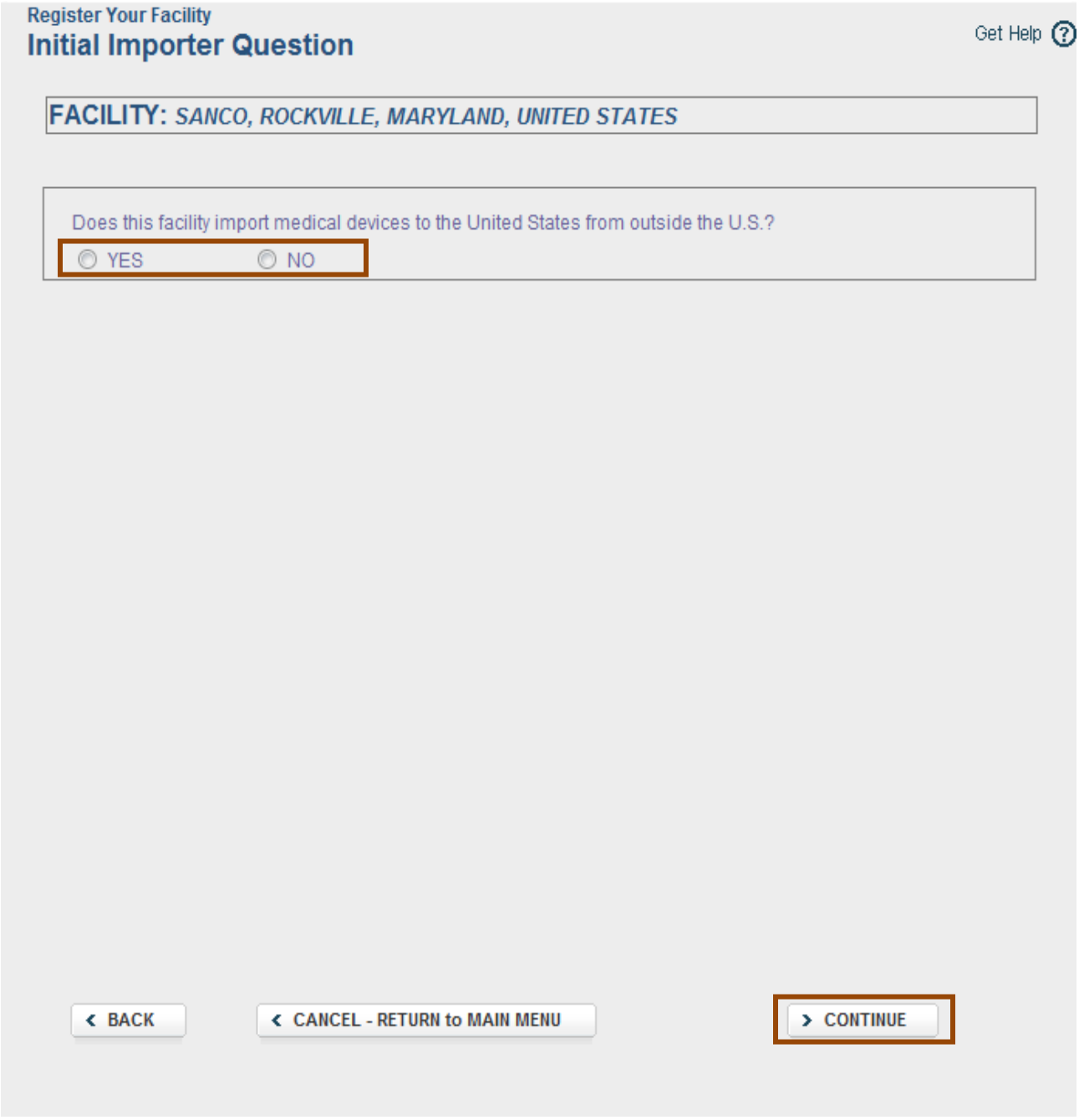


Step 9: On the Location Information page, enter the facility's physical address. If the facility's information matches that of either the owner/operator or official correspondent, click on the radio button next to owner/operator or official correspondent to autofill the location. You must also add any other business trade names for the facility. If known, you may also enter the facility DUNS number and thefacility URL. Then, click "Continue Registration." Proceed to Step 10.



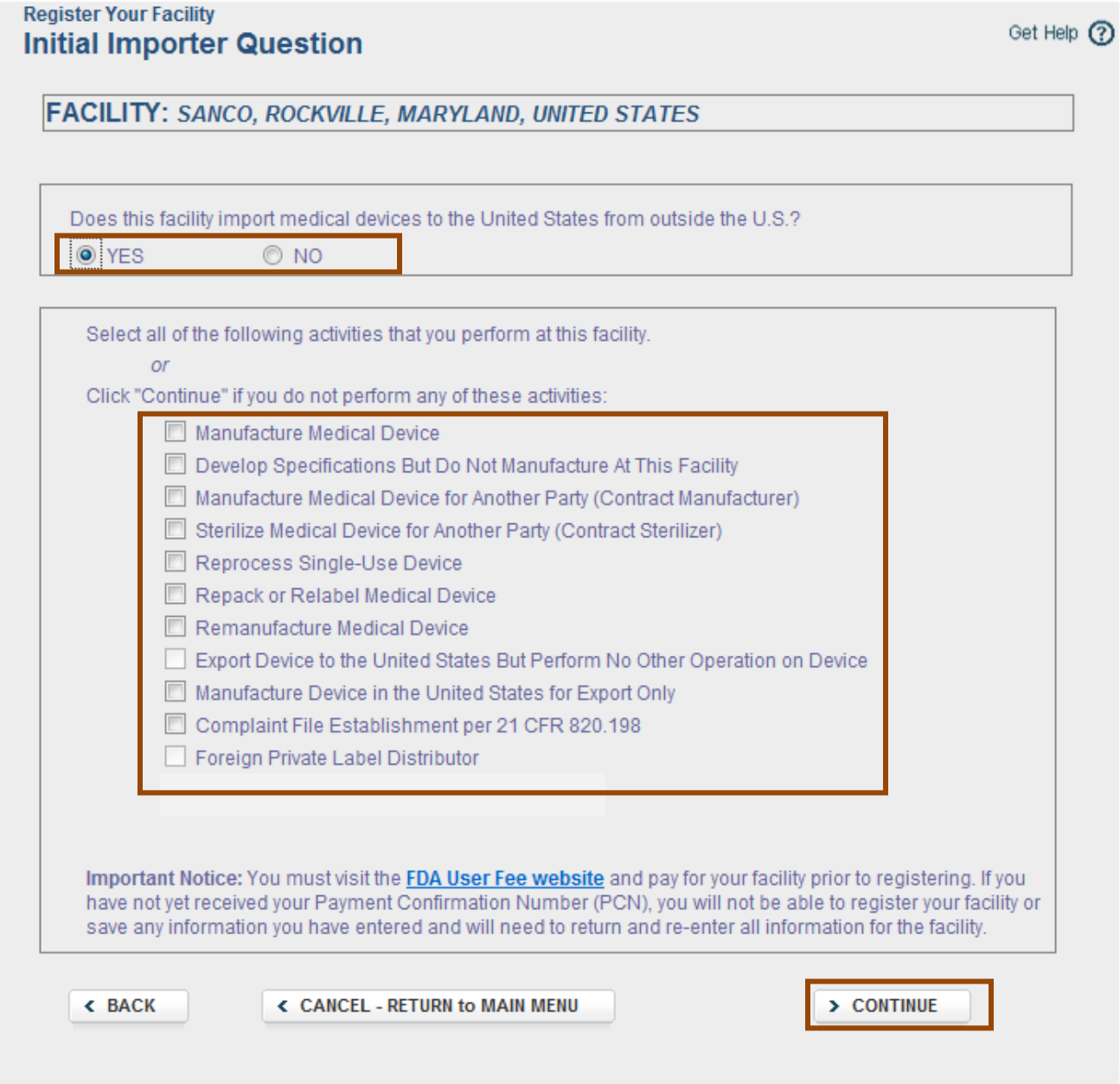
Step 10: On the Initial Importer Question page, select "No" if 1) the facility does not import medical devices from a foreign country or 2) if there are other activities associated with the devices that it imports. Click "Continue" and skip to Step 12A.

If the facility has no other activities associated with the medical devices that it is importing from a foreign country, select "Yes" and proceed to Step 11A.



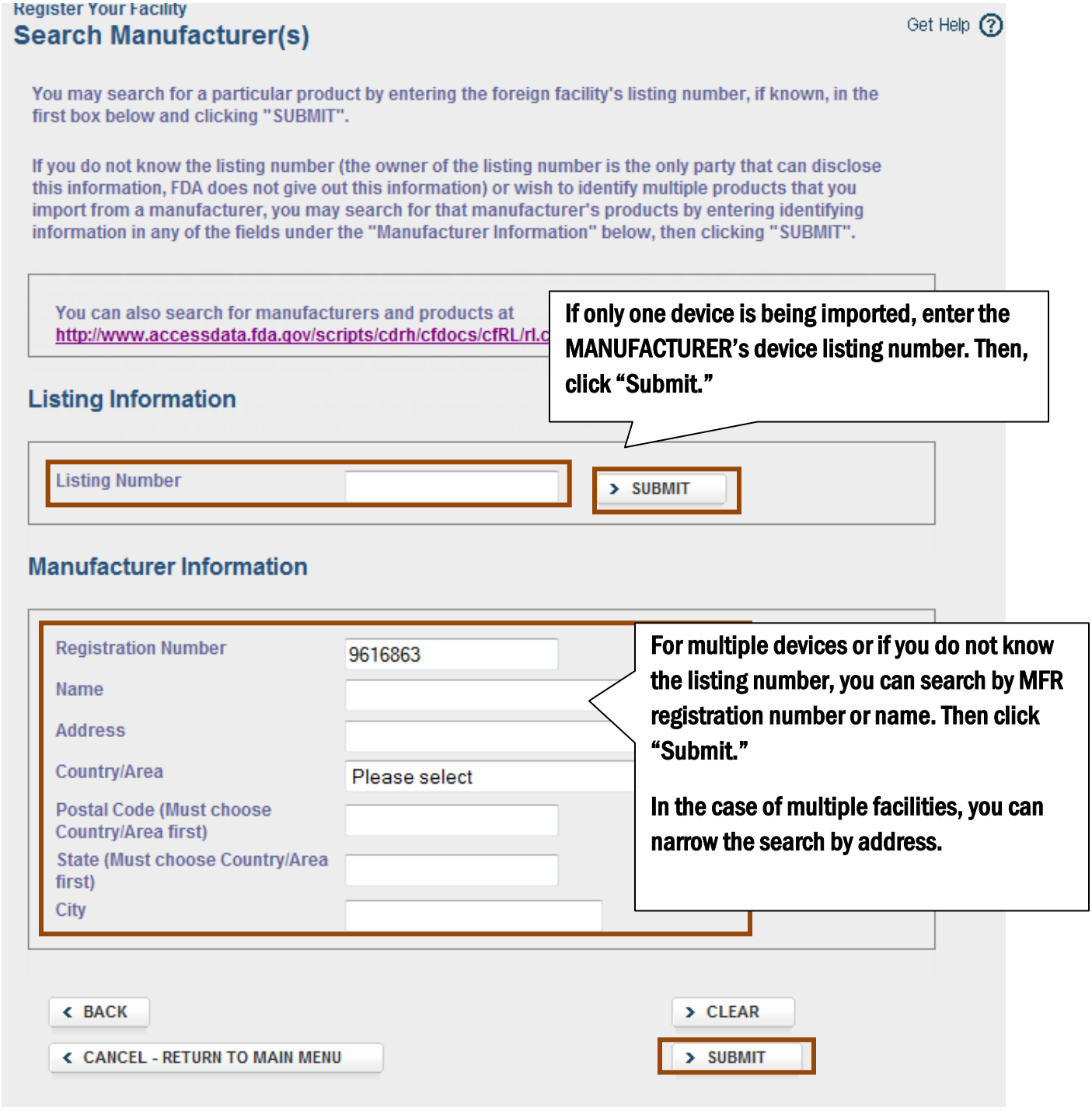
Step 11A: If you answered “Yes” to the Initial Importer Question, a list of activities will be displayed. If you perform other activites at this facility on devices that are not imported, select the activities that are performed and click “Continue”. Proceed to Step 12A.

If you do not perform any of the listed activities, leave all selections blank and click “Continue.” Proceed to Step 11B.



Step 11B: Click on “Search & Add MFR’s Products” and proceed to Step 11C.

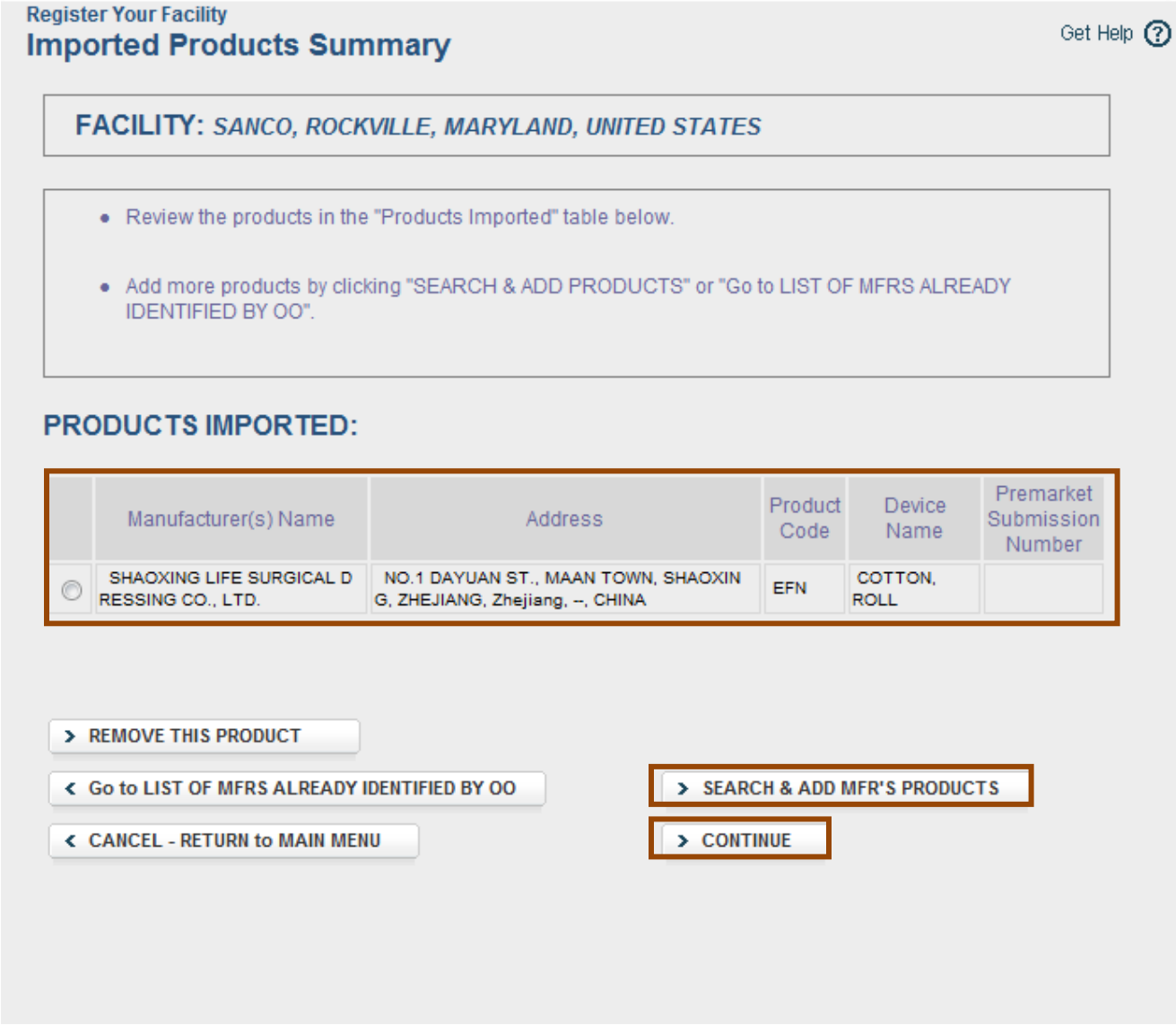
Step 11C: The Search Manufacturer(s) page provides a variety of ways to add the manufacturer of the imported device. When you have entered the device listing number or entered the manufacturer information, click “Submit.” Proceed to Step 11D.



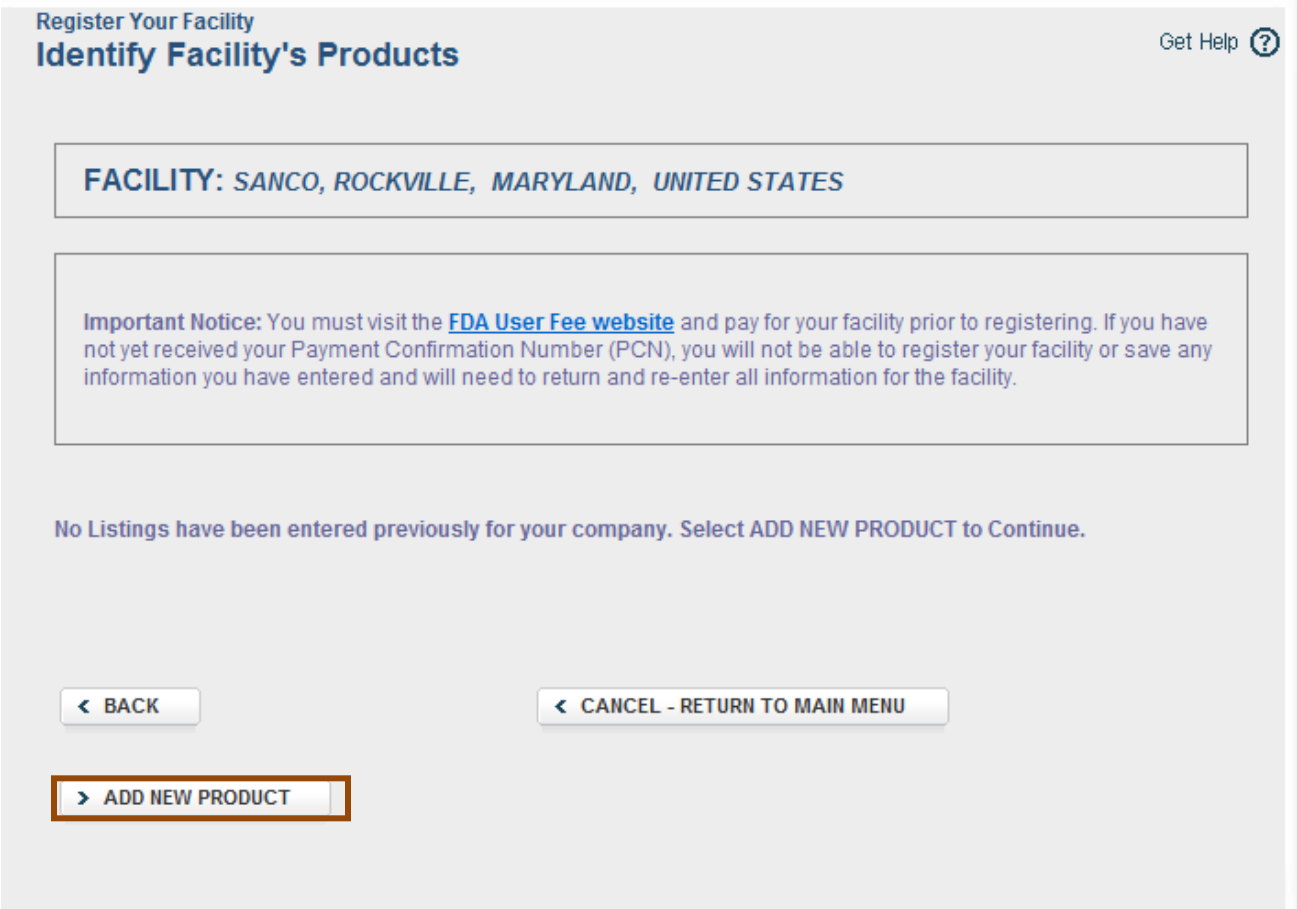
Step 11D: On the Importer – Identify Manufacturers of Products page, select the product(s) you import, then click “Add Selected Products.” Proceed to Step 11E.

Step 11E: On the Imported Products Summary page, preview the list of manufacturers/devices to ensure all submitted manufacturers / devices are listed. Then, click "Continue." Proceed to Step 16A.

If you need to add more products, click “Search & Add MFR’s Products” and return to Step 11C.



Step 12A: On the Identify Facililty's Products page, click "Add New Product". Proceed to Step 12B.



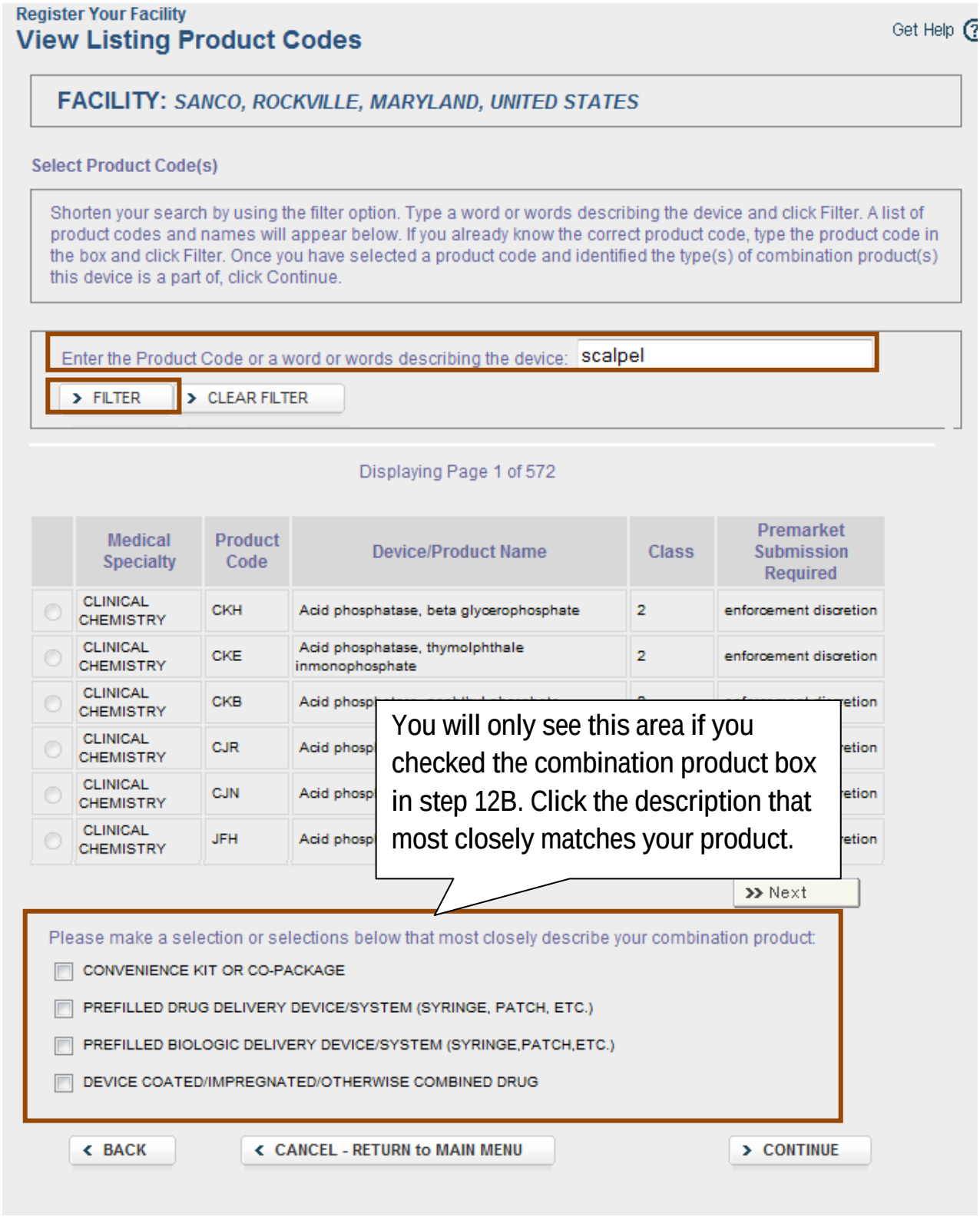
Step 12B: On the Enter Premarket Submission Number page, if the device is not exempt, enter the premarket submission number, and click "Continue." Proceed to Step 13.

If the device is exempt, click "Continue." Proceed to Step 12C.

If the device is part of a combination product that includes a drug or biologic, click the box (indicated below).

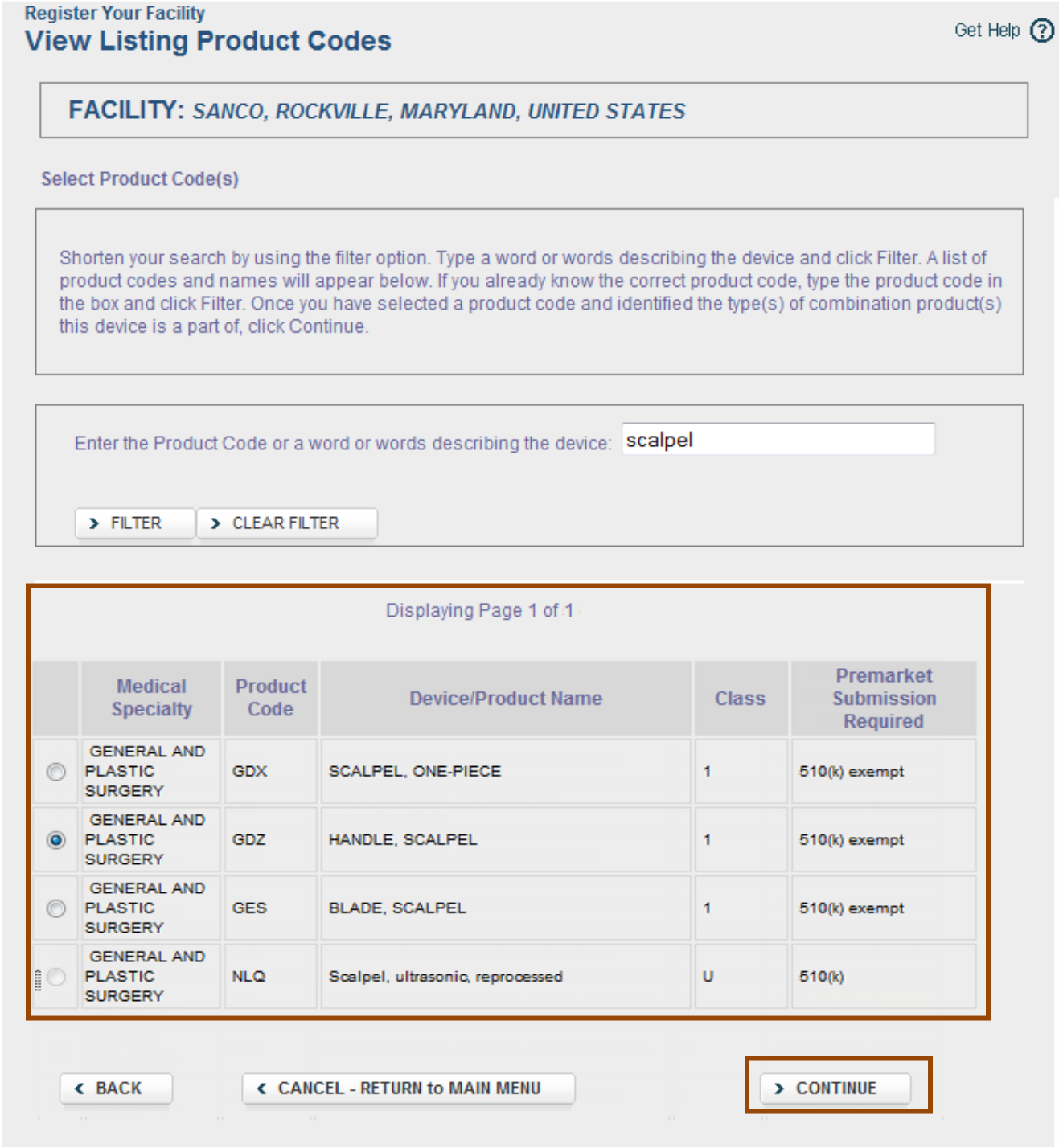
Step 12C: On the Exporter Question page, preview the question and click “Yes” or “No.” Click “Continue” to proceed to Step 12D.

Step 12D: If the device is exempt, enter the 3 letter FDA product code or word(s) that describe the device in the "Enter the Product Code or a word or words describing the device" text box on the View Listing Product Codes page. Click "Filter" to display a list of products. Proceed to Step 12E.



Step 12E: Click the radio-button next to your product code, and then click "Continue." Skip to Step 14A.

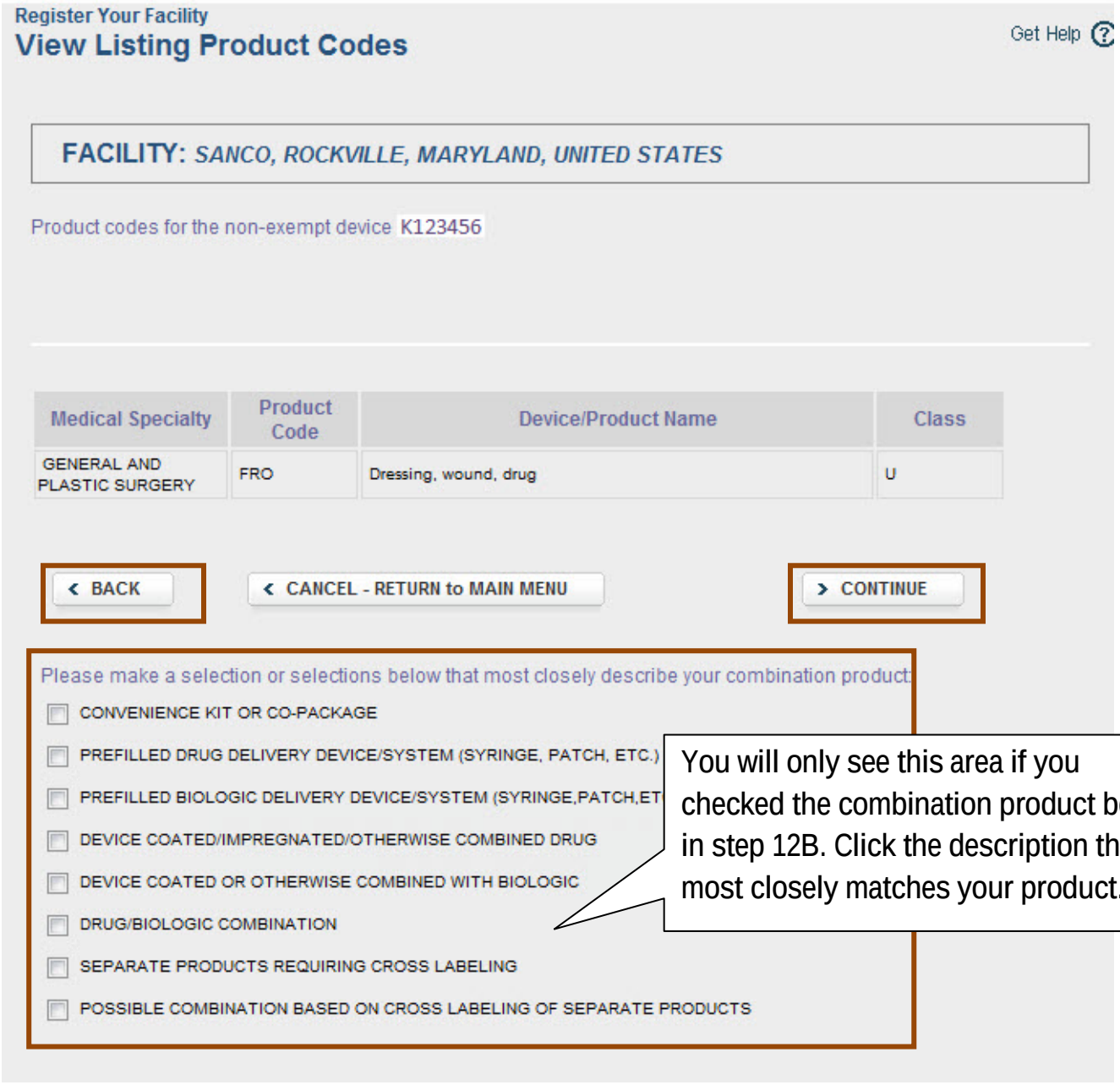
NOTE: If more than one page of potential product matches is generated, make sure to review all pages until you find the product code that matches your device.



Step 13: If a valid premarket submission number was entered, the product code will display. If the product code is correct, click “Continue”. If you think that an incorrect product code is showing for the premarket submission number entered, contact reglist@CDRH.FDA.GOV for assistance.

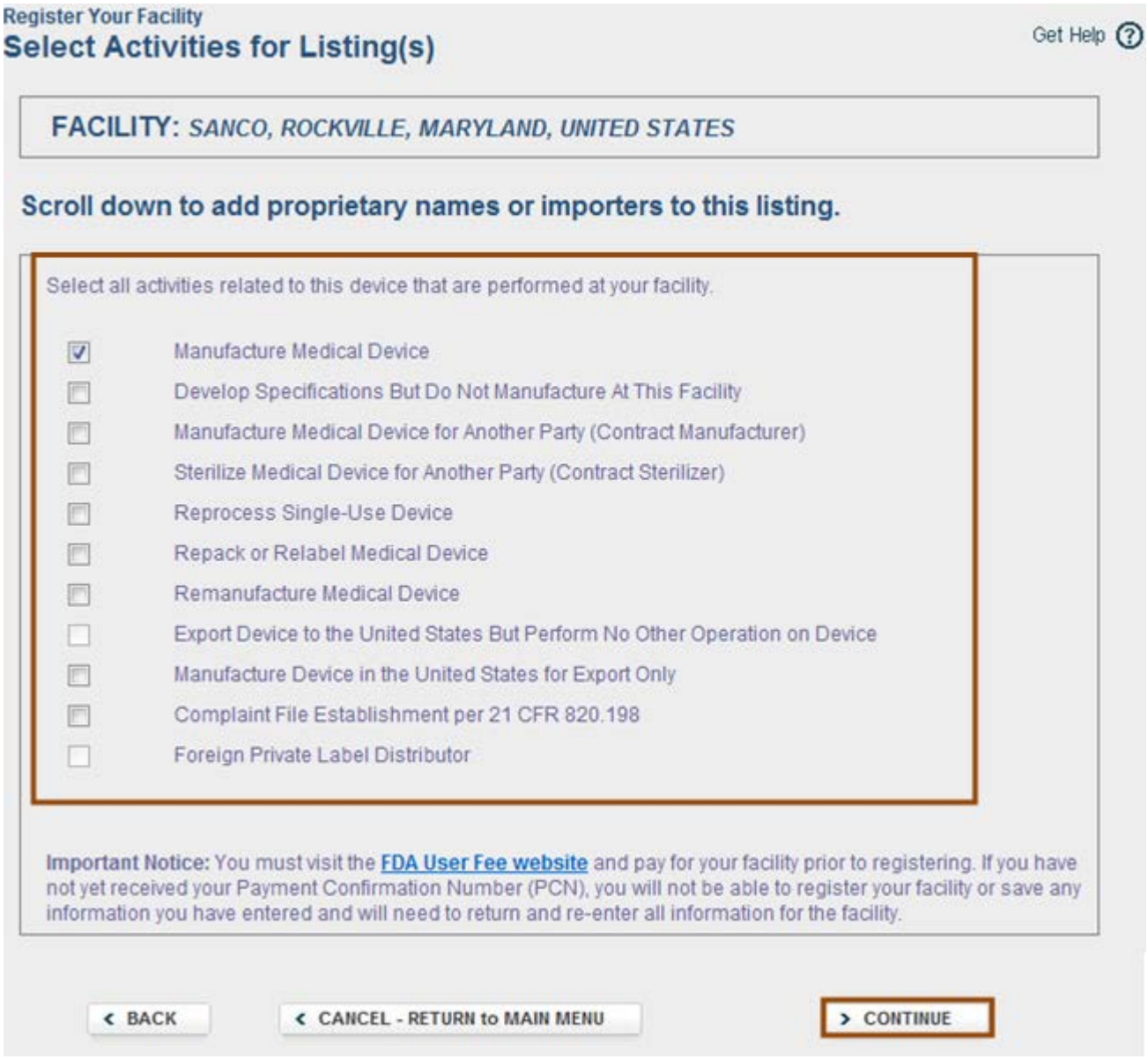
If an incorrect premarket submission number was entered, click “Back” to enter the correct number.

Proceed to Step 14A.

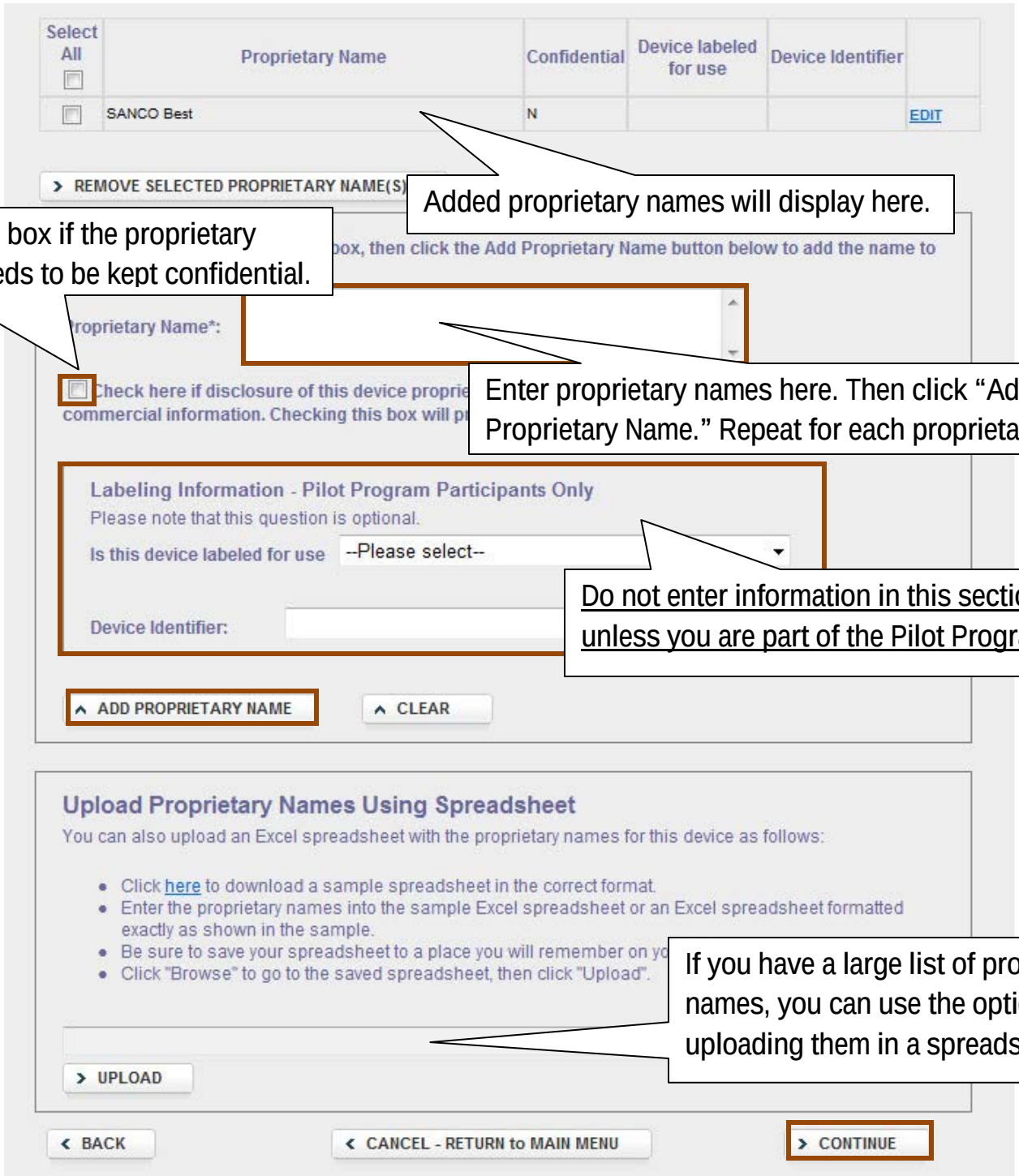


Step 14A: On the Select Activities for Listing(s) page, select the activities related to the device at this facility, and then click “Continue.”

Proceed to step 14B.

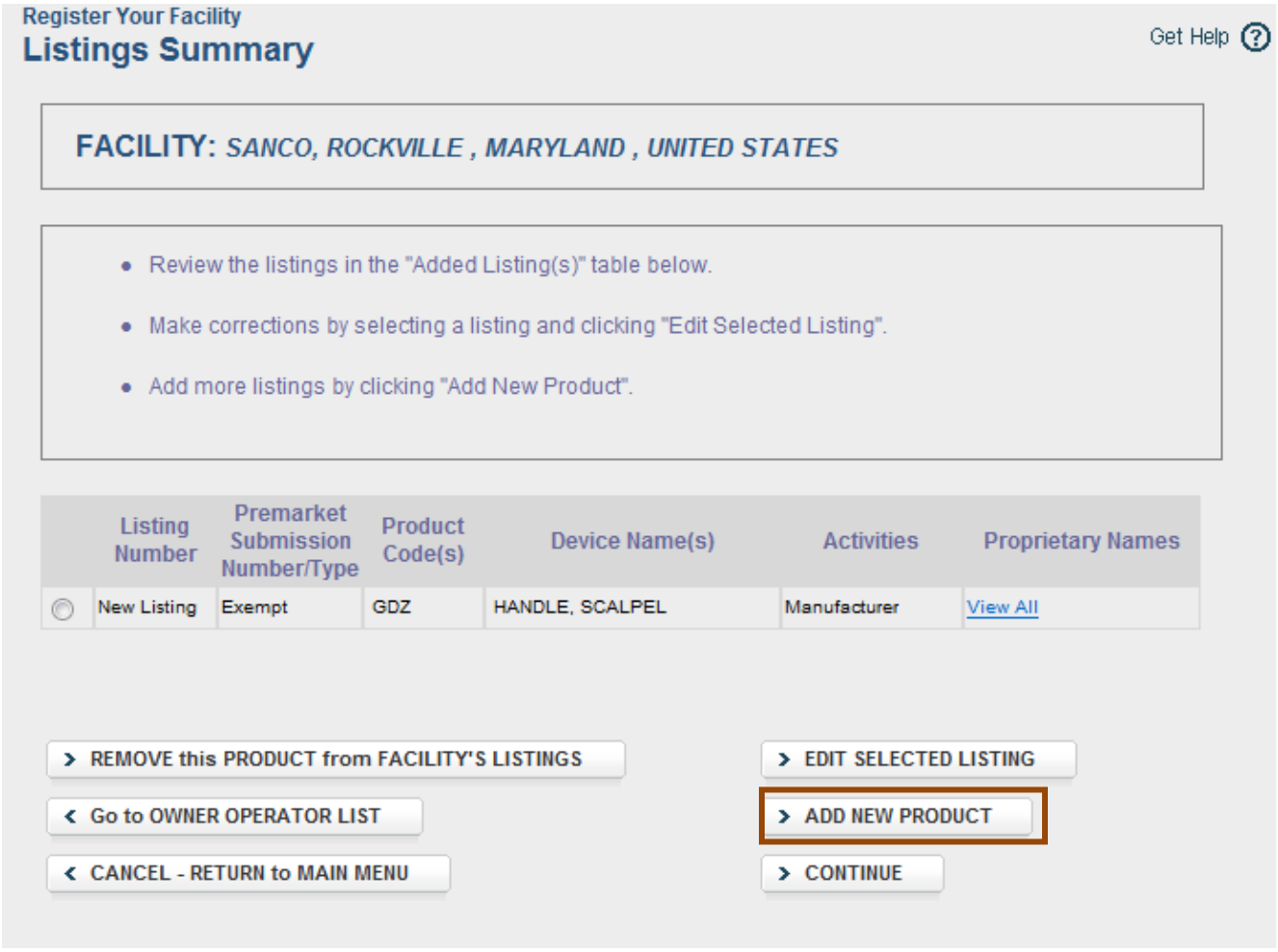


Step 14B: On the Enter Proprietary Name(s) page, enter the proprietary name(s) in the Proprietary name text box. Click “Add Proprietary Name” to move the entered name up to the Proprietary Name section. If the proprietary name needs to be confidential, check the disclosure statement box. Once all proprietary names have been added, click “Continue”. Proceed to step 15.



Step 15: On the Review Listings Summary page, review the device listing and click “Continue” if you do not have any more devices to be listed. Proceed to Step 16A.

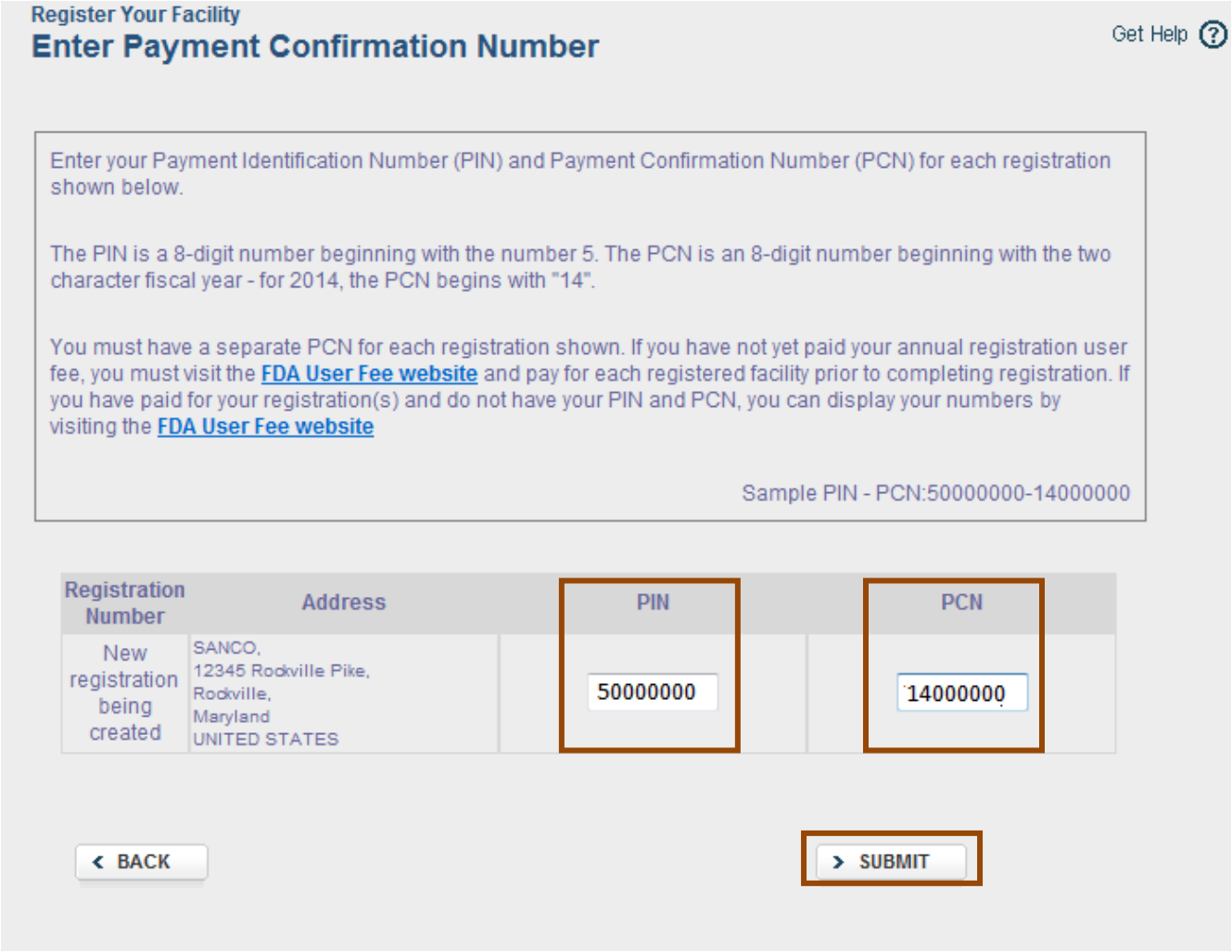
To add more devices to the list, click “Add New Product”, go to step 12A.



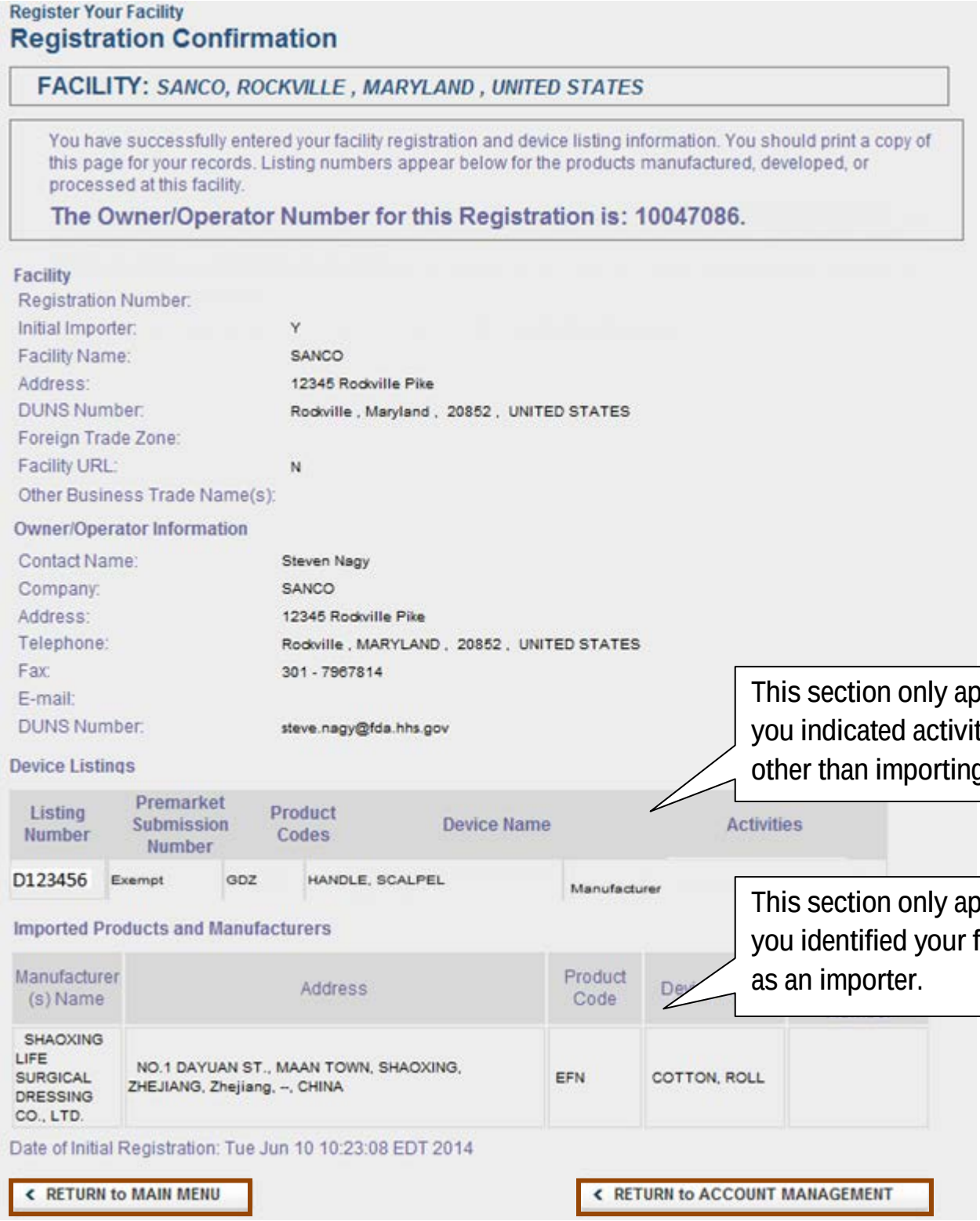
Step 16A: On the top half of the Registration Review page, review the facility and contact person information for accuracy. If the information is not accurate, click the appropriate “Edit” button and follow the prompts to make corrections. Proceed to Step 16B.

Step 16B: On the bottom half of the Registration Review page, review Imported Products & Manufacturers and Device Listings. If the information is not accurate, click the appropriate "Edit" button and follow the prompts to make corrections. If / when all information is correct, click the box next to the certification statement, and then click "Submit." Proceed to Step 17.

Step 17: On the Enter Payment Confirmation Number page, enter the 8-digit Payment ID Number (PIN) and 8-digit Payment Confirmation Number (PCN) and click “Submit.” Proceed to Step 18.



Step 18: The Registration Confirmation page displays the registration information you have entered. Return to the main menu to continue other registration and listing actions or return to the Account Management page to log out of the system. Proceed to Step 19.



Register Your Facility

Registration Confirmation

FACILITY: *SANCO, ROCKVILLE , MARYLAND , UNITED STATES*

You have successfully entered your facility registration and device listing information. You should print a copy of this page for your records. Listing numbers appear below for the products manufactured, developed, or processed at this facility.

The Owner/Operator Number for this Registration is: 10047086.

Facility

Registration Number:	
Initial Importer:	Y
Facility Name:	SANCO
Address:	12345 Rockville Pike
DUNS Number:	Rockville , Maryland , 20852 , UNITED STATES
Foreign Trade Zone:	
Facility URL:	N
Other Business Trade Name(s):	

Owner/Operator Information

Contact Name:	Steven Nagy
Company:	SANCO
Address:	12345 Rockville Pike
Telephone:	Rockville , MARYLAND , 20852 , UNITED STATES
Fax:	301 - 7967814
E-mail:	
DUNS Number:	steve.nagy@fda.hhs.gov

Device Listings

Listing Number	Premarket Submission Number	Product Codes	Device Name	Activities
D123456	Exempt	GDZ	HANDLE, SCALPEL	Manufacturer

This section only appears if you indicated activities other than importing.

Imported Products and Manufacturers

Manufacturer (s) Name	Address	Product Code	Device Name
SHAOXING LIFE SURGICAL DRESSING CO., LTD.	NO.1 DAYUAN ST., MAAN TOWN, SHAOXING, ZHEJIANG, Zhejiang, --, CHINA	EFN	COTTON, ROLL

This section only appears if you identified your facility as an importer.

Date of Initial Registration: Tue Jun 10 10:23:08 EDT 2014

< RETURN to MAIN MENU

< RETURN to ACCOUNT MANAGEMENT

Step 19: A confirmation email will be generated and sent to you with the following information:

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
10903 New Hampshire Ave., WO66 Room 2621
Silver Spring, Maryland 20993-0002

May 30, 2014

Name of Official Correspondent	ISTVAN NAGY
Address of Official Correspondent	12345 ROCKVILLE PIKE ROCKVILLE, MARYLAND 20852 UNITED STATES STEVE.NAGY@FDA.HHS.GOV
Owner Operator Number	10047086

Dear Sir or Madam,

We have received your registration and listing information for the following medical device establishment

Establishment Name	SANCO
Establishment Address	12345 ROCKVILLE PIKE ROCKVILLE, MARYLAND 20852 UNITED STATES

The information submitted has been processed and entered into the FDA Registration and Device Listing Database. Your device establishment is now considered registered. **You will be notified of your official registration number within 90 days.**

Once you receive a registration number, you are required to re-register on an annual basis from October through December. Failure to re-register every year will invalidate your registration and result in your device establishment and listing information being removed from the FDA Medical Device Registration and Listing Web site.